K113228

DEC - 1 2011

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name & Address
Mazor Robotics Ltd.
PO Box 3104,
7 HaEshel St.,
Caesarea Park South 38900,
Israel

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as St.,
Kfar Saba 44425,
Israel

2. Date Prepared: October 24, 2011

3. Device Name

Proprietary Name: Renaissance System

Common Name: Combination of:
1. Spinal Stereotaxic instrument; and
2. System, Image Processing, Radiological

Device Type and Classification:
1. 21 CFR 882.4560; Stereotaxic instrument
2. 21 CFR 892.2050; System, image Processing, Radiological

FDA Classification: Class II, Product Code HAW and LLZ

4. Predicate Devices

The Renaissance System is substantially equivalent to the following devices:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics	Renaissance System	K110911	April 28, 2011
Medtronic Navigation	StealthStation System	K050438 K022414	June 2, 2005 August 14, 2002

5. Device Description

The Renaissance System hosts guidance for spine procedures and intra-operative 3D image processing capabilities. It enables the surgeon to precisely position surgical instruments and/or implants. The planning of the surgical procedure and virtual placement of surgical instruments and/or implants (e.g. a screw) can be achieved through pre-operation planning based on the patients' CT scan. The "Scan-and-Plan" new feature enables intra-operative planning on the 3D Scan (formerly the C-Insight) image or on a 3D image uploaded from an external 3D image acquiring system (e.g., Medtronic O-arm). The new "Scan-and-Plan" feature replaces the need for a pre-operative CT scan and pre-operative planning, although this feature is still available in the system.

The modified Renaissance System also allows retrieving DICOM files from the hospitals' PACS system for operation planning purposes.

In addition, the modified Renaissance System enables the user to download MRI data and fuse it with CT data in order to provide the user with additional information on the patient's anatomy during the pre-operative planning stage.

6. Indications for Use

The Renaissance System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or percutaneous procedures.

Renaissance 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Renaissance System.

8. Performance Testing

The following Performance tests were performed on the Renaissance System:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrated that the modified software version meets its design requirements.

- Multiple acquisition Methods - Registration Accuracy. The registration accuracy test demonstrated that the modified Renaissance System has maintained its accuracy, as specified in the device design requirements.

9. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the modified Renaissance System are substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mazor Robotics Ltd.
% A. Stein – Regulatory Affairs Consulting
Ms. Ahava Stein
Consultant
20 Hata'as Street
44425 KFAR SABA
ISRAEL

DEC - 1 2011

Re: K113228
Trade/Device Name: Renaissance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: October 27, 2011
Received: November 1, 2011

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 1 - INDICATIONS FOR USE

510(k) Number (if known): K113228

Device Name: Renaissance System

Indications for Use:

The Renaissance System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or percutaneous procedures.

Renaissance 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

Prescription Use ___√___ OR Over-The-Counter Use ___

(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113228